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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/845,497	05/01/2001	Amina Odidi	9577-25 LAB	2340

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EXAMINER	
PRYOR, ALTON NATHANIEL	
ART UNIT	**PAPER NUMBER**
1616	

MAIL DATE	DELIVERY MODE
10/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/845,497	ODIDI ET AL.	
	Examiner	Art Unit	
	Alton N. Pryor	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *24 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,6-9,11,15-17 and 21-34* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,6-9,11,15-17 and 21-34* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's arguments, see paper, filed 7/24/07, with respect to 35 USC 112, 1st paragraph rejection have been fully considered and are persuasive. The rejection of claims 1,6-9,11,15-17,21-34 under 35 USC 112, 1st paragraph with respect to "non-permeable film" has been withdrawn.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,6-9,11,15-17,21-34 will not remain rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The specification does not explain what is meant by – a non-permeable polymeric film. What does the phrase mean? How is the drug in the film being used?

Response to Applicant's argument

Applicant is correct in that one skilled in the art would understand the meaning of "a non-permeable film".

Maintained Rejections

Applicant's arguments filed 7/24/07 have been fully considered but they are not persuasive. See argument below.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 17,21,23,30,33 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Hirashima et al (JP 03197421; 8/28/91). Hirashima teaches a controlled release tablet coated with 12 g ethyl cellulose and 8 g PEG (40 %). Hirashima teaches that the tablet comprises 250 mg ascorbic acid and 281.23 mg sodium ascorbate (total active = 531.23 mg). The total active falls within the 5-95% active required for the tablet of instant claims. The coat comprising 12 g ethyl cellulose falls within the range of about 5 to less than 50% by weight of polymer in the coat. Hirashima does not teach that the coating is non-permeable and soluble in a pH of above about 5. However, in the absence of unexpected results, one having ordinary skill in the art would have expected for the prior art coat to be non-permeable and soluble in a pH of above about 5. One would have expected this since the prior art coat comprises % PEG and % polymer (ethyl cellulose) that fall within the ranges of those ingredients required by the instant claims.

Response to Applicant's argument

A. Applicant argues:

1. Instant encasement coat comprises at the high ends 50% polymer (ethylcellulose) and 40 % PEG; whereas, Hirashima teaching is an

encasement coating comprising 60 % ethyl cellulose and 30 % PEG. In summary applicant argues that Hirashima does not teach or suggest the combination of about 5 to less than 50% by weight of polymer and 0.5%-30% by weight PEG that would provide a non-permeable which is soluble in a pH of above about 5 as claimed.

2. It would not be obvious to conclude that the coat of Hirashima would be non-permeable and soluble in a pH of above about 5.0. In fact Hirashima would be permeable and would not be soluble at any pH.

3. Instant invention requires a cellulose ester, whereas Hirashima employs ethylcellulose, which is not a cellulose ester. As a result, the coat taught by Hirashima would be permeable rather than non-permeable as claimed.

B. Examiner argues:

1. The amounts of PEG and ethylcellulose in Hirashima and instant invention differ only by 10% of each. Applicant does not provide a showing that the 10% difference would materially impact the invention. For this reason, the rejection of record is maintained.

2. Applicant makes statement to the coat of Hirashima being permeable and insoluble at any pH. However, Applicant does not provide data showing that the 10 % difference in both the

ethylcellulose and PEG would make the coat non-permeable and soluble at a pH of about 5.0.

3. Ethyl cellulose is defined as being a cellulose ester having film-forming capability. See Google search attached.

In summary, Applicant argues that the amounts of PEG and polymer used in the polymeric film of Hirashima differ from the amounts of PEG and polymer used in the polymeric film disclosed in the instant invention. Applicant also argues that the polymeric film disclosed in instant invention is non-permeable whereas the polymeric film disclosed in Hirashima is semi-permeable. Examiner argues that the amount of both PEG and polymer taught in Hirashima and instant invention only differs by 10% and for this reason it is necessary for the Applicant to show the criticality of these small differences. With respect to the polymer properties, both Hirashima and instant invention employ the same polymers, e.g., cellulose esters. Therefore the cellulose ester taught in Hirashima which is semi-permeable, would have the same property of being semi-permeable in the instant invention.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1,6-9,15-17,21-34 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for invention comprising polymeric films: polyvinyl acetate phthalate, methacrylic acid copolymers, does not reasonably provide

enablement for the polymeric film being cellulose esters. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims. Note instant invention requires the polymeric film to be non-permeable. The instant invention uses cellulose esters to formulate the non-permeable film. However USPN 6099859 at column 4 lines 10-28 and USPN 6106864 at column 4 lines 32-38 disclose that cellulose esters are semi-permeable rather than non-permeable.

Response to Applicant's argument

Applicant argues that Dolan (USPN 6106864) discloses that cellulose esters are semi-permeable rather than non-permeable. Dolan describes cellulose acetate as being both impermeable and semi-permeable. Applicant further argues "The cellulose esters chosen for the instant invention must be combined in the percentages claimed, and must provide the encasement coat with the features instantly claimed; be non-permeable and soluble in a pH of above about 5.0." Examiner argues that Applicant merely states that the correct percentages (claimed percentages) of cellulose esters would provide a non-permeable coat, which would be soluble in a pH of above about 5.0. However, Examiner further argues that Applicant does not provide experimental results to show that such a coat would be produced. Where the prior art shows uncertainty or suggest the opposite of the claimed invention, it is critical that applicant supports the invention claimed with experimental data.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1,6-9,11,15-17,21-34 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Dolan et al (USPN 6106864; 8/22/00) and Dong et al (USPN 5800422; 9/1/98) and Cheng on record (USPN 6099859; 8/8/00). Dolan teaches oral dosage forms of actives such as darifenacin. See column 2 lines 34-52. Dolan teaches that the matrix comprising the active can be formed into a multiparticulate and / or coated with an impermeable coating. See column 2 lines 53-57. Dolan teaches that the multiparticulate cores comprising the actives can also contain cellulose and lactose (compression aids). See column 3 lines 1-7. Dolan teaches that the ingredients can be formulated into a tablet which can be coated with shellac, phthalate derivatives (cellulose acetate phthalate, polyvinylacetate phthalate) as well as with semi-permeable coatings such as cellulose esters (ethyl cellulose, cellulose acetate) and acrylic polymers. See column 3 lines 7-38. Dolan does not teach the polymeric coating comprising 1) 5 up to less than 50% by weight polymer, e.g. ethyl cellulose 2) 0.5 to 30% PEG. Dolan is silent to the amount of polymer in the coating. Therefore, in the absence of unexpected results showing the significance of the instantly claimed amount of polymer, the ideal amount of polymer used in Dolan may have fallen within the instant range of polymer amount being claimed. With respect to the polymeric film comprising PEG. Dong discloses the use of PEG in a capsule film coating. Note, Dong uses 25 %

PEG in the polymer coating which falls within the instantly claimed range amount. Cheng teaches that PEG is a flux-enhancing agent. A flux-enhancing agent allows the drug to be released through the pores of the polymeric coating. It would have been obvious to one having ordinary skill in the art to modify the invention of Dolan to include the PEG to enhance the release of the drug through the pores of polymeric coating. Although claims require the polymeric material to be non-permeable, it is noted that the claims employ polymeric films such as cellulose esters and acrylic polymers which are semi-permeable. For this reason the rejection appears to be proper. Note the property of the polymeric coating being soluble at a pH above 5.0 and having an extended release of the active over 12 hours are inherent properties of the polymer (cellulose esters) and PEG being used.

Response to Applicant's argument

Applicant argues:

1) Dolan teaches that impermeable coating is provided with an aperture. Ethyl cellulose is not a cellulose ester.

2) Dolan does not teach / suggest an encasement coat being non-permeable and soluble in pH of above about 5.

3) Declaration provided by Applicant on 3/8/04 shows that Cheng teaches the use of non-enteric cellulose esters and non-dissolving polymers and as a result Cheng's formulation yields a different release profile of the drug.

4) The specific percentage ranges instantly claimed provide unexpected results in comparison to Cheng and hence, in comparison to Dolan since similar coatings are used in Dolan.

Examiner argues:

1) Dolan teaches that the coating can be made using ethyl cellulose. None that the instant claims recite that the coating can comprise ethyl cellulose. According to a Google search ethyl cellulose is a cellulose ester possessing film-forming properties.

2) Dolan teaches that the coating can be formed of ethyl cellulose which produces a semi-permeable coating as depicted in column 3 lines 31-38 of Dolan. Dolan also teaches that ethyl cellulose can be employed to form an impermeable coat as depicted in column 3 lines 11-21. There is no mention of a non-permeable coat in Dolan as recited in the claims. Since ethyl cellulose can be used to form impermeable as well as semi-permeable coats, it would be necessary for applicant to show what kind of coating is produced with the specific percentages claimed. Note Dolan does not teach or suggest a non-permeable membrane. Dolan defines an impermeable membrane as one that allows no significant transport of the active across it during the intended release period of the formulation. See column 3 lines 11-21. Dolan defines semi-permeable membrane as one that allows transport of an active across it. See column 3 lines 31-38. Again, Dolan does not make mention that the ingredients employed therein would produce a non-permeable membrane. In fact the formulation of a non-permeable membrane is not even mentioned in Dolan. For this reason, it is imperative that Applicant shows that his invention produces a non-permeable

membrane using a cellulose ester since Dolan only teaches the production of impermeable and semi-permeable membranes using ethyl cellulose. Note Google defines ethyl cellulose as a cellulose ester.

3) The combination of Dolan with Dong and Cheng yields a coating comprising ethyl cellulose (cellulose ester) and PEG in the percentage ranges claimed. As a result it would be inherent for the properties of the coat produced by the combination of the references to have the same properties as the coat produced in the instant claims, i.e. non-permeable and soluble at a pH of above about 5.0. Note, Dolan and Dong produces a coating comprising ethyl cellulose and PEG. Cheng is being employed in the rejection to show the significance of PEG as a flux-enhancing agent.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Telephonic Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Alton N. Pryor whose telephone number is 571-272-0621. The examiner can normally be reached on 8:00 a.m. - 4:30 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Johann Richter can be reached on 571-272-0646. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Alton Pryor
Primary Examiner
AU 1616